REMARKS

With this amendment, claims 1-19 are pending.

Claims 1, 2, and 4 have been amended. Support for the amendments to claims 1, 2, and 4 may be found, for example, in the application as published[1] in paragraphs [0048] and [0058], and in the Figures.

I. 35 U.S.C. §112

Reconsideration is requested of the rejection of claim 1 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Office asserts that Applicant's use of the term "optionally" with respect to the element of an outer ridge in claim 1 makes it unclear whether a ridge is required as part of the claimed implant, thereby rendering the metes and bounds of the claim unclear.

Without addressing the merits of the rejection and in an effort to expedite prosecution of the application, Applicant has deleted the term "optionally" from claim 1. Claim 1 now defines a boundary structure that defines, along with the inner ridge, the secondary drainage region. Moreover, the boundary structure has a height from the plate which is less than that of the inner ridge.

Accordingly, the rejection as applied to claim 1 is rendered moot.

II. 35 U.S.C. §102(b)

Reconsideration is requested of the rejection of claims 1-3, 5-7, 10, 14, 16, 18, and 19 under 35 U.S.C. §102(b) as being anticipated by Molteno.[2]

Claim 1, as amended, is directed to an ophthalmic implant for treating or alleviating the symptoms of glaucoma. The implant comprises (a) a plate shaped to fit the surface of an eye when implanted, (b) an inner ridge located on the upper surface of the plate, where a region encompassed by the inner ridge defines a primary drainage region into which fluid from the anterior chamber or posterior chamber of the eye can be

[1] The application as published is Patent Application Publication No. US 2007/0249984.
[2] Molteno, U.S. Patent No. 4,750,901.

drained when in use, (c) a boundary structure located on the upper surface of the plate outward of the inner ridge, provided that the height of the inner ridge relative to the surface of the plate is greater than the height of the boundary structure relative to the surface of the plate, (d) a secondary drainage region outside the inner ridge into which fluid from the primary drainage region can be received when in use, where the secondary drainage region is defined by the inner ridge and the boundary structure, and (e) a hole in the inner ridge having a size enabling a drainage tube for draining the fluid from the anterior chamber or posterior chamber of the eye to the primary drainage region to be connected to the hole so that fluid can be transferred through the tube and into the primary drainage region.

Claim 16 is directed to a method of treating or alleviating the symptoms of glaucoma using an implant of claim 1. The method comprises (a) surgically inserting the implant between the sclera and Tenon's tissue of the eye, and (b) inserting the drainage tube through the surface of the eye and into either the anterior chamber or posterior chamber of the eye to allow fluid to drain from the anterior chamber into the drainage region of the implant.

Thus, the implant of claim 1, which is also utilized in the method of claim 16, specifically has a boundary structure wherein the height of the inner ridge relative to the surface of the plate is greater than the height of the boundary relative to the surface of the plate. The boundary structure may have any height less than that of the inner ridge, including no height. In the latter instance, the boundary structure corresponds to the edge of the plate.

Molteno discloses an implant designed to prevent post-operative hypotony in glaucoma patients. The implant has two elevated ridges on the upper surface of the plate: an elevated peripheral ridge and a secondary elevated ridge. The peripheral ridge runs around the edge, or near to the edge, of the plate to help define and maintain a bleb into which fluid from the eye can drain and be absorbed into the overlaying Tenon's tissue. The subsidiary ridge defines a second smaller region within the area of the plate defined by the peripheral edge. Notably, therefore, Molteno requires (1) an

inner and outer ridge, and (2) shows in Fig. 2 that the inner ridge 7 is of a lesser height than the outer ridge 3, ***precisely the opposite of what is now claimed***.

Molteno is Applicant's own prior disclosure. The Examiner is referred to paragraph [0058] of the current application as published. Molteno is distinguished by Applicant on exactly the same basis articulated in this amendment.

In order for a reference to anticipate a claim, it must disclose each and every element of the claim.[3] In this instance, Molteno fails to disclose an implant having a boundary structure wherein the height of the inner ridge is greater than the height of boundary structure. Notably, Molteno is Applicant's own prior disclosure, and the Examiner is referred to paragraph [0058] of the current application as published, where Molteno is distinguished by Applicant on exactly the same basis articulated in this amendment.

In particular, when the claimed implant is free of the outer ridge (i.e., has a boundary structure having no height) the claim does not read on Molteno, as Molteno specifically requires a two-ridged (inner and outer ridged) implant. Thus, the relationship between the concomitant boundaries of the primary and secondary drainage regions is not disclosed in Molteno.

When the claimed implant has an outer ridge, the height of the inner ridge is greater than the height of the outer ridge. Molteno, however, does not disclose any specifics relative to the height of the two elevated ridges of the implant disclosed therein other than the drawings which show the height of the outer ridge to be greater than that of the inner ridge. In the absence of disclosing a difference in height between these two ridges other than one opposite to that which is claimed, it cannot be asserted that the requirement of an implant having two ridges wherein the height of the inner ridge is greater than the height of the outer ridge is disclosed in Molteno.

Thus, as each and every element of claim 1 is not disclosed in Molteno, claim 1 is not anticipated by Molteno. Claims 2, 3, 5-7, 10, and 14, each of which depend from

[3] MPEP 2131; *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

claim 1, are patentable over Molteno for the reasons stated with respect to claim 1 and by reason of the additional requirement each claim introduces.

Claim 16 is directed to a method of treating or alleviating the symptoms of glaucoma using an implant of claim 1. As claim 1 is novel over Molteno for the reasons stated above, so too is claim 16 directed to the use of such an implant. Moreover, claims 18 and 19, which depend from claim 16, are patentable over Molteno for the reasons stated with respect to claim 16 and by reason of the additional requirements each claim introduces.

III. 35 U.S.C. §103(a)

A. Molteno

Reconsideration is requested of the rejection of claims 4, 8, 9, 12, and 15 under 35 U.S.C. §103(a) as being unpatentable over Molteno.

Claim 1 is set forth above. Claims 4, 8, 9, 12, and 15 depend from claim 1 and further define the implant of claim 1.

Molteno is set forth above.

Initially, Applicant notes that claim 4 is not listed by the Office as being unpatentable over Molteno. However, as the Office addresses claim 4 with respect to Molteno, Applicant assumes claim 4 should have been listed as being rejected and is treating the claim accordingly.

Notably, Molteno is Applicant's own prior disclosure. Thus, Applicant can say with confidence that Molteno neither disclosed the invention now being claimed nor provided any teaching of the current invention. Moreover, the Examiner is reminded that there are no formulaic rules of obviousness. *In re Ochiai*, 37 USPQ 2d 1127, 1122 (Fed. Cir. 1996). Applicant has invented a new relationship between the boundaries of the primary and secondary drainage regions that provides advantages and new results for ophthalmic implants. Moreover, common sense suggests that the nearly 20 year span from Applicant's first disclosure (i.e., Molteno) to the current disclosure is strong evidence that the difference now asserted was not obvious to those of ordinary skill in the art, as it ***clearly was not even obvious to the Applicant himself***.

The Office asserts that "it would have been obvious to one having ordinary skill in the art at the time of the invention to eliminate the outer ridge disclosed by Molteno if the fluid-retention properties of the outer ridge are not desired,"[4] citing to MPEP §2144.04 for the proposition that omission of an element and its function is obvious if the function of the element if not desired.

However, elimination of the outer ridge (or the reduction in the height of the outer ridge relative to the inner ridge) is not the result of the simple desire to eliminate the function of the same. Instead, the removal of the outer ridge, or in the alternative the reduction in the height of the same relative to the height of the inner ridge, is pursued in order to overcome significant problems associated with the implant described in Molteno. As noted previously, Applicant has invented a new and beneficial relationship between the primary and the secondary drainage areas that was not obvious to Applicant when he made the invention disclosed in Molteno.

Following insertion of this implant, Tenon's tissue is stretched over the surface of the plate. As fluid drains from the interior of the eye into the primary drainage region defined by the inner ridge, pressure builds against the tension provided by the Tenon's tissue. When the pressure reaches a certain level in the primary drainage region, fluid then flows over into the secondary drainage region on the plate defined by the boundary structure. However, due to the height of the outer ridge being greater than (according to the figures) the inner ridge, the Molteno implant causes the tension across the cavity to be less than desirable.

Thus, in order to solve this problem it was devised that reducing the height of the outer ridge, or removing it altogether, results in the tension of the Tenon's tissue across the primary drainage region defined by the inner ridge to be substantially reduced ***without compromising the size of the plate***. That is to say, more than simply reducing the tension of the Tenon's tissue, the reduction in height of the outer ridge or the removal of the outer ridge altogether also advantageously allows for maintenance of a plate size with sufficiently large surface area to cause formation of a sufficiently large bleb. The result is the improved connection between the inner ridge and the tissue of

[4] Office action dated November 16, 2009, page 4.

the eye.[5] Moreover, the absence of an outer ridge or the presence of an outer ridge having a height less than the height of the inner ridge also advantageously allows improved ease of insertion of the implant into the eye, and reduces the need for multiple plate implants and the surgical problems associated with the same.[6] Thus, the elimination of the outer ridge or the reduction in the height of the outer ridge relative to the inner ridge is not simply the elimination of an element as the result of the desire to eliminate the element's function and is, therefore, nonobvious.

Moreover, adjustment of the outer ridge height or elimination of the outer ridge entirely is neither described nor suggested by Molteno. In fact, the issues addressed by the presently claimed implant – namely, the reduction in the tension of the Tenon's tissue without compromising the size of the plate of the implant – and the advantages achieved as a result thereof – namely, improved connection between the inner ridge and the tissue of the eye, improved ease of insertion of the implant, and a reduction in the need for multiple plate implants and the surgical problems associated with the same – are not even contemplated by Molteno.

Thus, in the absence of disclosing the elements of adjustment of the outer ridge height or elimination of the outer ridge entirely or of providing a reason or suggestion to modify or combine the cited references to achieve the same, a *prima facie* case of obviousness has not been established with respect to claim 1. Claims 4, 8, 9, 12, and 15, each of which depend from claim 1, are patentable over Molteno for the reasons stated with respect to claim 1 and by reason of the additional requirements they introduce.

B. Molteno in view of Speckman et al.

Reconsideration is requested of the rejection of claims 13 and 17 under 35 U.S.C. §103(a) as being unpatentable over Molteno in view of Speckman et al.[7]

Claim 1 is set forth above. Claim 13 depends therefrom and further defines the implant of claim 1.

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[5] Application as published (US 2007/0249984), paragraphs [0046], [0049], and [0060].
[6] Application as published (US 2007/0249984), paragraphs [0047], [0048], and [0058].
[7] Speckman et al., U.S. Patent No. 5,338,291.

Claim 16 is set forth above. Claim 17 depends therefrom and further defines the implant of claim 1.

Molteno is set forth above.

Speckman et al. disclose a glaucoma shunt device. In describing Figure 4, Speckman et al. disclose that in order to prevent excess drainage of aqueous humor from the anterior chamber in the early post-operative period, the flow of fluid through the catheter to the episcleral plate is restricted by a biodegradable ligature that is tied around a portion of the catheter.[8]

As discussed above, nothing in Molteno discloses or suggests adjustment of the outer ridge height or elimination of the outer ridge entirely. Moreover, the issues addressed by these features of the presently claimed implant – namely, the reduction in the tension of the Tenon's tissue without compromising the size of the plate of the implant – and the advantages achieved as a result thereof – namely, improved connection between the inner ridge and the tissue of the eye, improved ease of insertion of the implant, and a reduction in the need for multiple plate implants and the surgical problems associated therewith – are not even contemplated by Molteno.

Speckman et al. do nothing to remedy these deficiencies. Speckman et al. disclose a glaucoma shunt having a temporary and biodegradable ligation to restrict the flow of the aqueous humor and prevent overdrainage. However, nothing therein discloses or addresses adjustment of the outer ridge height of or elimination of the outer ridge entirely from the implant device. In the absence of disclosing these elements or providing a reason or suggestion to modify or combine the cited references to achieve the same, a *prima facie* case of obviousness has not bee established with respect to claims 1 and 16 or to claims 13 and 17 which, respectively, depend therefrom.

[8] Speckman et al., U.S. Patent No. 5,338,291, column 5, lines 59-67.

CONCLUSION

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. §112, of the rejection of claims 1-3, 5-7, 10, 14, 16, 18, and 19 under 35 U.S.C. §102, and of the rejection of claims 8, 9, 12, 13, 15, and 17 under 35 U.S.C. §103(a), and allowance of all claims as presented herein.

Applicants request an extension of time to and including March 16, 2010, for filing a response to the above-mentioned Office action. The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 19-1345.

Respectfully submitted,

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